IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

In re: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	)	**Master Case No. 1:14-cv-01748 MDL No. 2545**
This document relates to:	)	
Jesse Patridge and Shirley Patridge,	)	**Case No. 1:14-cv-7960**
Plaintiff,	)	
v.	)	
AbbVie Inc., and Abbott Laboratories, Inc.,	)	**COMPLAINT AND DEMAND FOR JURY TRIAL**
Defendants.	)	

COMPLAINT

Plaintiffs, Jesse Patridge and Shirley Patridge, individual, complaining against Defendants, AbbVie Inc. and Abbott Laboratories Inc., state as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription drug AndroGel, which is manufactured, sold, distributed and promoted by the Defendants AbbVie Inc. and Abbott Laboratories Inc. (hereinafter jointly "Defendants" or "AbbVie") as a testosterone replacement therapy.

2. Defendants misrepresented that AndroGel is a safe and effective treatment for hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. AndroGel is an exogenous form of the androgen testosterone. It regulates the expression of platelet TXA_2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. AndroGel is delivered transdermally and is applied to the skin in the form of a gel. It is available in either a 1% or 1.62% concentration.

5. Defendants failed to adequately warn physicians about the risks associated with the AndroGel and the monitoring required to ensure their patients' safety.

6. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for AndroGel. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T", an abbreviated term for low testosterone.

7. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

8. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "Low T". Additionally, low testosterone is not a disease

recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

9. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially. This has directly related to AndroGel's sales increasing to over $1.37 billion per year.

10. Consumers of AndroGel and their physicians relied on the companies false representations and were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

B. PARTIES

11. Plaintiffs are and were at all times relevant hereto, residents and citizens of Cynthiana, Harrison County, Kentucky.

12. Defendant AbbVie is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

13. Defendant Abbott Laboratories Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, North Chicago, Lake County, Illinois 60064.

14. By way of background, Unimed Pharmaceuticals Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division which included AndroGel. Then in 2013, Abbott created AbbVie, a

company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

C. JURISDICTION AND VENUE

15. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

16. This Court has personal jurisdiction of the Defendants because the Defendants have their primary place of business in Illinois.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, inter alia, a substantial part of the events or omissions giving rise to the Plaintiff's claims occurred in, and because the Defendants transact business in, this district.

D. FACTUAL BACKGROUND

1. General Allegations

18. This action is for damages brought on behalf of the Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

19. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

20. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use and application by men, including, but not limited to, Plaintiff.

21. At all times herein mentioned, Defendants were authorized to do business within the states of Tennessee and Illinois.

22. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

23. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug AndroGel is safe and free from serious side effects, and

Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

24. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

25. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

26. In men, testosterone levels normally begin a gradual decline after the age of thirty.

27. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

28. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy. (AndroGel 1.62% was approved in April, 2011). After FDA approval, AndroGel was widely advertised and marketed by Defendant as a safe and effective testosterone replacement therapy.

29. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

30. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men." The Defendant represented to the FDA that it would market and sell the drug to this patient population of one million men who have an actual diagnosis of hypogonadism with an associated medical condition. This was a false representation that it made to the FDA in order to obtain approval of the drug.

31. In 2000, when the FDA approved AndroGel, the company announced that the market had increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 - 2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription. A Canadian study showed that only about 6.3% of men who were prescribed testosterone actually met the diagnostic criteria for hypogonadism.

32. At all times material hereto, and since the time that AndroGel first received approval from the FDA, the Defendants knew and understood the FDA-approved indications for clinical use of the AndroGel product.

3. Direct to Consumer Marketing and Promotion to Physicians for Unbranded/Off-Label Use.

33. Defendants expanded the indications for use by promoting and detailing “Low T” as an acquired form of hypogonadism, and advantaged intentional ambiguity in the AndroGel product labeling as a basis for “label expansion” and “off-label” marketing, detailing, and promotion to physicians.

34. In 2000, when reviewing the drug's advertisements, the FDA told AndroGel's maker that "claims and representation that suggest that AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." The drug, the FDA said, was only approved for men with hypogonadism. Despite this admonition from the FDA, the Defendants continued to market and promote testosterone replacement therapy for “andropause” and “Low T”.

35. Defendants coordinated a massive advertising campaign targeted toward men who did not have Hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. The direct to consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called “Low T”, which was a term for low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare

providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

36. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

37. Defendants’ national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", “Are you sad and/or grumpy?”, and “Do you have a lack of energy?”

38. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, “Don’t make it too long and make it somewhat sexy.” Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has “no trouble calling it a crappy questionnaire” and that it is “not ideal.” This is

the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. TIMES.

39. Since the FDA approved AndroGel for a very specific medical condition called Hypogonadism, Defendants have also sought to convince primary care physicians that Hypogonadism is synonymous with "Low T" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

40. While running its disease awareness campaign, Defendants promote their products as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

41. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

42. The Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "Low T", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

43. A 2004 memo on AndroGel sales strategies said the sales force was putting extra emphasis on rural areas, since "rural doctors are typically very accessible, give us plenty of time to teach them the right way to diagnose and treat, and they have the patients."

44. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

45. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

46. Defendants' advertising paid off in a return of $1.4 billion in sales during the past year (2013), making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are*

Testosterone Drugs the Next Viagra?, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

47. In 2009, a whistle-blower lawsuit filed by relator John King and Jane Doe on behalf of the United States and 23 individual states alleged that AndroGel was marketed and promoted for off-label uses, including osteoporosis, sexual dysfunction, depressions and obesity.

48. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. *See* Singer, *Selling That New-Man Feeling*, *supra*; See *also*, Larry Dobrow, *All-star large pharma marketing team of the year: Androgel*. Jan. 2, 2013, Medical Marketing & Media, *available at:* http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

49. The Defendants engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T".

50. The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of AndroGel is safe for human use as a treatment for "Low T", even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

51. At all times material hereto, Defendant's marketing strategy included the use of sales or drug detailing representatives ("reps") and marketing and brand team personnel who

performed on-line and in-person AndroGel product detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

52. The Defendant's drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the AndroGel product, as well as discount and/or rebate coupons to give to patients for the purchase of AndroGel.

53. Defendant's drug "reps" detailed and marketed AndroGel to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

54. Defendant denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

55. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

56. The Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

57. Defendants marketed, promoted, and detailed AndroGel for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the AndroGel product.

58. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

59. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

60. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

61. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

62. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

63. The FDA did not, and never has, approved AndroGel for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or,

g. bone strength or density abnormalities.

4. Adverse Events and Serious Health Risks Caused by TRT.

64. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

65. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

66. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels[2]. It can also cause increased platelet aggregation and vasoconstriction.

67. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

68. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of

[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

69. The clinical trial data submitted to the FDA for the approval of AndroGel showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

70. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

71. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up,

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

72. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

73. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

74. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

75. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

76. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

77. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

78. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

79. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

80. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol. [16] Impaired contractile function results in numerous cardiovascular injuries and disease.

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[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.

[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.

[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

81. A study published in 2007 compared blood levels of testosterone and *estradiol* in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of *estradiol* in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, *estradiol* levels in these heart attack patients were **180%** higher, while bioavailable testosterone levels were **nearly three times less** than those of control patients.[18]

82. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[19]

83. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant

[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.

[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006**Vol.** 290**no.** H2043-H2050**DOI:** 10.1152/ajpheart.01121.2005

increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

84. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

85. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

86. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

87. In a study published in 2013[21], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and

[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

88. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

5. Inadequate Warnings and Labeling

89. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

90. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

91. AbbVie's advertising program, sought to create the image and belief by consumers that the use of AndroGel was a safe method of alleviating their symptoms, had few

side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

92. Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

93. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroGel. Defendants deceived potential AndroGel users and their physicians by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

94. Defendants concealed material relevant information from potential AndroGel users, and their physicians, and minimized user and prescriber concern regarding the safety of AndroGel, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

95. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represent that AbbVie adequately tested AndroGel for all likely side effects. The Defendants

also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

96. AndroGel's prescribing information and medication guide contained within the package materials do not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

97. The medication guide contained within the package materials instructs patients to tell their healthcare provider the following before initiating use of AndroGel:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

However, the prescribing information and medication guide contained within the package materials fail to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. They also fail to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease, which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

98. The prescribing information and medication guide contained within the package materials do warn that the use of the product may result in increased red blood cell count, but do not instruct physicians or patients that it can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count does not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

99. The prescribing information and medication guide contained within the package materials do instruct physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, but they fail to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also fail to instruct physicians to monitor their patient's hematocrit more frequently.

100. The prescribing information and medication guide contained within the package materials fail to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.. They also fail to instruct physicians

to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

101. The prescribing information and medication guide contained within the package materials do warn that use of the product may result in risk of blood clots in the veins, but they specifically limit this warning to "blood clots in the legs" and only warn against blood clots in the legs that form as a result of increased red blood cell count (polycythemia). There is no warning for blood clots in the veins other than "blood clots in the legs", nor is there any warning of blood clots resulting from causes other than polycythemia. Also, there are no warnings that blood clots in veins as a consequence of polycythemia could result in pulmonary embolism, or other injuries secondary to the formation of deep vein thrombosis in the legs or other parts of the body.

102. The prescribing information and medication guide contained within the package materials fail to warn that use of the product may result in elevated levels of estradiol. They do not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There is also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

103. The prescribing information and medication guide contained within the package materials do not warn that use of the product may result in the formation of deep vein

thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

104. The prescribing information and medication guide contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There is no mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. Instead, the label only states that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

105. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ("Vigen Paper").

106. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

107. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ("Finkle Paper").

108. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

109. The increased incidence of heart attack and stroke was foreseeable at the time of the product launch of AndroGel 1% and 1.62%.

110. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration (FDA) announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

111. As a result of this mandate by the FDA, on June 21, 2014, the Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE, and also updated the medication guide for AndroGel to include the significant risk of PE as follows: "Blood clots in the legs or lungs. Signs and symptoms of a blood clot in your leg can

include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain." However, the prescribing information and the medication guide contained within the package materials still lacks any warning about the risks of elevated estradiol levels, the need to screen for underlying clotting traits, and they contains no warnings for strokes, or for cardiovascular injuries.

112. The marketing and promotion of the product to patients and physicians overstated its benefits by creating the impression that it was a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

113. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff and his physician had known the risks and dangers associated with AndroGel, the physician would not have prescribed nor would Plaintiff would have taken AndroGel and consequently would not have been subject to its serious side effects; and/or, Plaintiffs' physicians would have adequately monitored Plaintiffs' hematocrit and estradiol levels, and, as a result, Plaintiffs' injuries would have not otherwise have occurred

6. Case Specific Facts

114. Plaintiff is 72 years old. Plaintiff sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him by Abbott and AbbVie through direct-to-consumer educational and information "Low T" awareness campaigns propagated by Abbott and AbbVie.

115. Abbott and AbbVie sought to raise the awareness of physicians, including Plaintiff's physician, with respect to a condition denominated as "Low T," and to educate physicians about "Low T" and its treatment.

116. Abbott and AbbVie had a duty to warn prescribing physicians about the risks of AndroGel use, including the risks of cardiovascular events and cerebrovascular accident.

117. Plaintiff's physician would not have prescribed AndroGel to his patient, Plaintiff, had he been advised of and warned of the risks of deep vein thrombosis caused by or increased with respect to the risk of harm by AndroGel.

118. On or about, April 15, 2010 commenced treatment with AndroGel, after being prescribed this medication by his primary care physician.

119. Plaintiff continued treatment with AndroGel, as prescribed by his primary care physician, through May 18, 2011.

120. On or around January 12, 2011, Plaintiff began to experience leg pain and presented to Harrison Memorial Hospital in Cynthiana, Kentucky for diagnosis and treatment. Plaintiff was hospitalized from January 12, 2011 to January 19, 2011, during which time, Plaintiff was diagnosed with deep vein thrombosis and started on blood thinners.

121. Plaintiff's injuries were directly and proximately caused by or increased in the risk of harm by his use of testosterone by the mechanism of injury as described above in Section I. D. 4.

122. Because of his use of the AndroGel, Plaintiff suffered deep vein thrombosis and continues to suffer:

a. Cardiovascular and ambulatory impairment;

b. loss of life's pleasures;

c. fear and fright;

d. embarrassment and humiliation;

e. economic loss;

f. requirement for medical monitoring relating to his injuries;

g. loss of earnings; and,

h. past, present and future medical expenses.

123. Plaintiff was not informed during any of his hospitalizations or treatment that his cardiovascular injuries were related in any way to his use of TRT.

124. Prior to very recently, Plaintiff was unaware of any connection between his use of AndroGel and his deep vein thrombosis.

125. Plaintiff incurred significant medical expenses as a result of the treatment he underwent to treat his injury, will incur future medical expenses as his injury is permanent, lost wages as a result of being unable to work, his ability to labor and earn money has been impaired, he is at increased risk for future health problems and disability, and he suffered physical pain and mental anguish.

126. Defendants materially and deceptively misrepresented and mischaracterized the definition of hypogonadism to the Plaintiff and his physician.

127. There was no warning to Plaintiff or his physician that the product presented a risk of thromboembolic events beyond a “clot in the leg.”

128. Had Plaintiff and his physicians known the true risks associated with the use of testosterone medications, including AndroGel, he would not have consumed the AndroGel, and/or would have been adequately monitored for its side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of AndroGel.

II. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

129. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

130. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

131. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

132. Defendants failed to adequately warn consumers and/or their health care providers that AndroGel could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

133. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking AndroGel it was necessary to frequently monitor hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

134. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of AndroGel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

135. As a direct and proximate result of Plaintiff's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

Count Two – Negligence

136. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

137. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of AndroGel.

138. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of AndroGel to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and it sequelae, pulmonary embolism, and sudden cardiovascular death.

139. Defendants had a duty of care when it undertook to provide comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; and, to educate and inform consumers and patients about "Low T;" and, to provide consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

140. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of AndroGel to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

141. Defendant's duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

-hypogonadism and its diagnostic criteria;

-the FDA-approved indications for the clinical use of the AndroGel product;

-the clinical safety and effectiveness profiles of AndroGel; and,

-appropriate, complete, and accurate warnings concerning the adverse effects of AndroGel, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

142. At all times herein mentioned, Defendants breaches its duty of care by negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and failed to adequately test and warn of the risks and dangers of AndroGel as described herein.

143. The Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion, and as a result millions of men, including the Plaintiff, were prescribed AndroGel unnecessarily, and therefore needlessly exposed to serious health risks for which there were no or inadequate warnings.

144. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for AndroGel, including Plaintiff's prescribing

physician. Specifically, the FDA had not approved AndroGel or any other testosterone-containing preparation for the treatment of "Low T."

145. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing product AndroGel with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

146. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonable, dangerous side effects, Defendants continued to market AndroGel to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that AndroGel marketing materials claim are caused by "Low T".

147. At all times material hereto, Defendants misbranded the AndroGel product on an on-going and continuous basis, and failed to warn physicians and patients that AndroGel was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

148. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with AndroGel use.

149. As marketed, detailed, and promoted to physicians, including Plaintiff's prescribing physician, Defendants failed to warn that AndroGel caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

150. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

151. Defendants' negligence was a proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Three – Breach of Implied Warranty

152. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

153. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.

154. Specifically, the Defendants warranted to Plaintiff that its product was intended to treat a condition called "LowT" and that it was safe and fit for that use, but the Defendants failed to disclose that "LowT" is not a recognized medical condition and that its testosterone product was not FDA approved to treat any such condition.

155. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including AndroGel, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using AndroGel. As a result, the Plaintiff used Defendants' product as it was warranted to be intended.

156. AndroGel was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that AndroGel has dangerous propensities when used as intended and will cause severe injuries to users.

157. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Four - Breach of Express Warranty

158. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

159. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that AndroGel was FDA approved to treat a condition called "LowT", and that it is safe, effective, fit and proper for its intended use. Plaintiff purchased AndroGel relying upon these warranties.

160. In utilizing AndroGel, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that there is no disease or medical condition called "LowT" that is recognized by any medical community, peer-reviewed journal, or learned treatise, and that AndroGel is unsafe and unfit for its purported intended uses.

161. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Five - Fraud

162. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

163. Through a sophisticated and well-orchestrated marketing campaign, the Defendant set out to invent a fictitious disease/medical condition that it called "LowT", and then purposely deceived the Plaintiff and his physicians into believing that this was a real disease/medical condition and that Plaintiff suffered from it. Defendant did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "LowT". Those commonly occurring conditions were listed in the "Is It LowT Quiz", and included:

- Being tired after dinner
- Diminished ability to play sports
- Lack of energy
- Being sad
- Being grumpy
- Decreased libido

Each of these purported "symptoms" of "LowT" are normal and common conditions for men over the age of 40, and especially common in men over the age of 50.

164. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel, and up to the present, knew that their product could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of its product could

result in a dramatic increase in serum estradiol levels, yet the Defendant willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

165. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroGel. Defendants knew of the foregoing, that AndroGel is not safe, fit and effective for human consumption, that using AndroGel is hazardous to health, and that AndroGel has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

166. Defendants knowingly, falsely, deceptively, and inaccurately designated the physiologic decrease in men's testosterone levels and the age-related symptoms men experience with aging as a form of acquired hypogonadism with the intent to deceive physicians into prescribing Androgel for "off-label" indications for clinical use; and, to engage in "label expansion" of the AndroGel product; and, to drive increasing consumer and patient demand for AndroGel prescriptions.

167. Defendants knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of AndroGel to physicians, to include statements concerning the effectiveness of treatment of the age-related signs and symptoms included on the "Interactive ADAM Questionnaire." There was no double-blind, placebo-controlled, randomized, sufficiently powered, and independent study or clinical investigation or clinical evidence to support this use of AndroGel, and no approval by the FDA to warrant promotion of these indications for clinical use.

168. Defendants knowingly, falsely, deceptively, and inaccurately designated and represented that the physiologic decline in men's testosterone levels and the age-related symptoms men experience with advancing age, as a form of "acquired hypogonadism" with the intent to confuse and deceive consumers and patients, and to foster the belief by consumers and patients, including Plaintiff, that they harbored a "disease" or pathologic medical condition that was appropriately treated with the AndroGel product.

169. Defendants concealed and suppressed the true facts concerning AndroGel, and the actual disease for which it has been FDA approved to treat (Hypogonadism), with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe AndroGel, and Plaintiff would not have used AndroGel, if they were aware of the true facts concerning its dangers.

170. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of a mass marketing effort to encourage patients to seek treatment for "Low T," while having actual knowledge that AndroGel was not indicated for the treatment of "Low T," nor was it proven to be clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

171.

172. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that it provided to consumers and patients through its multi-platform marketing, promotional, educational, and awareness campaigns concerning the AndroGel product and its indications for clinical use; and further knew that consumers and

patients would make treatment choices and exercise treatment options about their use of the AndroGel product in reliance upon this information.

173. Defendants deceived physicians by explicitly or implicitly claiming that the treatment of "Low T" was an FDA-approved clinical indication for use of AndroGel, when in fact it was an "off-label" indication for clinical use.

174. Consumers, including Plaintiff, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for AndroGel and the clinical safety and effectiveness profiles for AndroGel, including information concerning the "off-label" use of the AndroGel product.

175. Plaintiff relied on the fraudulent and deceptive representations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that AndroGel was FDA approved to treat a condition called "LowT", and that the Defendant's testosterone drug was a safe and effective treatment for his "LowT".

176. Plaintiff would not have sought or continued treatment for "Low T" or administered AndroGel had he been provided with adequate, true, accurate, and correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of AndroGel, and the fact that "Low T" was not an FDA-approved indication for clinical use of AndroGel.

177. Plaintiff would not have sought or continued treatment for "Low T," or administered AndroGel, had he been provided with adequate, true, accurate, and correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of AndroGel to treat "Low T."

178. During the detailing, marketing, and promotion to physicians, neither Defendants nor the co-promoters who were detailing AndroGel on behalf of Defendants warned physicians, including Plaintiff's prescribing physician, that AndroGel caused or increased the risk of harm of cerebrovascular accident and neurologic injuries.

179. Defendants, through its national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including Plaintiff, about a "disease" Defendants denominated and characterized as "Low T."

180. These materials did reach Plaintiff, and he relied upon these materials in reaching his decision to purchase, use, and continue the use of AndroGel throughout his course of testosterone therapy.

181. Plaintiff would not have administered AndroGel to himself had the educational and informational materials made available to him by Defendants, and upon which he relied to his detriment, informed him about the risks of cardiovascular events and cerebrovascular accident with product use.

182. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Negligent Misrepresentation

183. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

184. From the time AndroGel was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that "LowT" was an actual disease/medical condition for which medical treatment was indicated, and that AndroGel was safe, fit, effective, and FDA approved for human consumption to treat "LowT". At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

185. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

186. The representations by the Defendants were in fact false, in that AndroGel is not safe, fit and effective for human consumption, using AndroGel is hazardous to health, and AndroGel has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

187. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of AndroGel.

188. Plaintiff relied on the misrepresentations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that AndroGel was FDA approved to treat

a condition called "LowT", and that the Defendant's testosterone drug was a safe and effective treatment for his "LowT".

189. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use AndroGel. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used AndroGel. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

190. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Seven Design Defect

191. Defendant participated in the manufacture, sale and marketing of an exogenous testosterone drug that was FDA approved to treat a specific medical condition called Hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

192. The Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "Low T", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

193. Defendant manufactured, sold, and promoted this drug which contained a defective condition because the design was defective and unsafe in that it caused serious injuries

and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

194. This design defect made the drug unreasonably dangerous, yet the Defendant knowingly introduced the drug into the market.

195. The drug as manufactured by the Defendant remained unchanged and was in the same condition at the time of the injury hereafter alleged.

196. As a direct and proximate cause of Defendant's manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injury.

Count Eight – Loss of Consortium

197. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

198. At all relevant times stated herein, Plaintiff Shirley Patridge was and is the wife and spouse of Plaintiff Jesse Patridge.

199. As a result of the injuries sustained by Plaintiff Jesse Patridge as set forth above, Plaintiff Shirley Patridge has suffered loss of consortium, including but not limited to, mental anguish and the loss of her husband's support, services, society, companionship, comfort, affection, love, and solace.

200. As a result of the injuries sustained by Plaintiff Jesse Patridge, as set forth above, Plaintiffs Jesse and Shirley Patridge sustained damage to their marital relationship.

Punitive Damages Allegations

201. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

202. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other AndroGel users and for the primary purpose of increasing Defendants' profits from the sale and distribution of AndroGel. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

203. Prior to the manufacturing, sale, and distribution of AndroGel, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel.

204. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in AndroGel and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in AndroGel. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of AndroGel knowing these actions would

expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

205. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against the Defendant, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiffs:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: October 13, 2014

Respectfully submitted,

/s/ Trent B. Miracle

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